At the 1924 Radiological Society of North America’s annual meeting, physician Malvern Clopton announced that simple palpation or visual inspection could not detect early breast cancer. Clopton’s call for a better method of breast cancer detection emphasized surgical excision of suspected lesions, because early attempts at radiography of the breast produced poor-quality images. By the 1960s, radiologists had continued to refine techniques, and although the direct-capture images took at least 5 seconds of exposure time and would not be considered acceptable diagnostic quality by today’s standards, consistent use of mammography had begun.¹

The 1970s ushered in use of xeromammography, which resembled photocopying techniques and provided excellent edge enhancement. However, introduction of xeromammography caused workflow issues: the images were printed on paper with a blue powder and did not require a lightbox as film did. In addition, image contrast was inverted for radiologists because masses appeared dark and fatty tissue was light. Eventually, concerns about radiation dose and other problems led radiologists back to film-screen methods for mammography.¹

Substantial improvements in mammography technology have been made since xeromammography and the first clinical trials on screening mammography as a tool for breast cancer detection.¹² Each new improvement in imaging technology is evaluated primarily for its clinical value, or whether the new method improves detection and diagnosis of disease.³ Typically, clinical performance parameters include specificity, sensitivity, and cancer detection rates.³ Each new technology also can temporarily disrupt quality, efficiency,
and workflow. Ultimately, however, digital mammography and digital technologies save time and improve workflow, which leads to better efficiency and higher quality patient care.

The ability to acquire, transmit, store, interpret, and compare breast images electronically has been a primary step in bringing mammography in line with other diagnostic imaging modalities by facilitating integration with administrative and other clinical functions. The radiologist now can correlate information from different digital breast imaging modalities using the same workstation.

**History of Digital Mammography**

Development of digital mammography began in the 1970s but took several decades to refine; the U.S. Food and Drug Administration (FDA) approved the first digital unit for clinical use in 2000. Adoption was not immediate, partly because of cost but also because of reluctance on the part of physicians about spatial resolution and quality of digital mammograms compared with film-screen mammograms. Concerns about the planning and process changes required to implement digital mammography also might have caused hesitation.

Results from clinical trials continued to be studied following the modality’s introduction. The largest and perhaps most important trial was the Digital Mammographic Imaging Screening Trial (DMIST) conducted by the American College of Radiology (ACR) Imaging Network in 2005. DMIST demonstrated that digital mammograms were clinically comparable to film-screen mammograms and superior in sensitivity for women younger than 50 or for those who have dense breasts. Subgroup analyses from the trial, which involved more than 33 sites throughout the United States and Canada, also showed that digital mammograms were not as accurate as film-screen images in helping to detect breast cancer in older women who had fatty breasts, but these findings led to efforts to improve acquisition and display technology to overcome this shortcoming in digital mammography.

In addition to its clinical value, radiologists and leaders in breast imaging recognized other advantages of digital mammography over film-screen examinations including:

- Improved workflow.
- Lower likelihood of lost, misplaced, or damaged examinations.
- Ability to electronically transmit images for teaching and consultation.
- Facilitation of image archiving and electronic access for interpretation and comparison.
- Reduced radiation dose to the patient.
- Wider dynamic range.
- Quicker needle localization procedures.
- Easier integration of computer-aided detection (CAD).
- Improved integration with radiology information systems (RIS), picture archiving and communication systems (PACS), and breast imaging reporting systems.

Despite advantages, critics pointed out the increased costs of digital mammography. The transition from film-screen to digital mammography and CAD increased costs to the Medicare fee-for-service program from $666 million annually to $962 million annually over a 6-year period. In addition, according to Killelea et al, no statistically significant change in tumor detection of early-stage cancers occurred among the covered population during the same period. Another criticism of digital mammography has been the modality’s relatively high recall rate, leading to unnecessary follow-up imaging for a greater number of women.

Despite criticisms, the shift to digital mammography after DMIST was gradual but steady and pervasive. The National Breast and Cervical Cancer Early Detection Program, a national program in the United States that offers free or low-cost screening mammograms to women who have low incomes or who lack insurance coverage, noted that in 2010, nearly half of women in the program received digital mammograms. By 2014, digital mammography constituted more than 90% of the entire U.S. breast cancer screening market. More than 12,374 of the 13,243 units certified under the Mammography Quality Standards Act (MQSA) were full-field digital mammography units as of February 1, 2014. In essence, digital mammography has replaced film-screen methods and is considered the modality of choice for breast cancer screening.
Advances in digital technology have contributed to improved breast cancer screening outcomes. When screening mammography reveals a suspicious finding, the patient typically is referred for diagnostic breast ultrasonography, breast magnetic resonance (MR) imaging, or digital breast tomosynthesis (DBT). An emphasis on breast density and laws requiring patients who have dense breasts to be notified could affect the follow-up imaging pattern. Density notification had been passed as legislation in at least 24 states as of fall 2015.

The notification informs a woman about a radiologist’s finding of a high amount of fibroglandular tissue and often requires that the woman be encouraged to explore additional screening options with her providers. Density notification usually is included in the patient letter required by the MQSA after a mammogram. A congressional bill has been proposed to make density notification a federal standard.

Studies continue on the role of DBT in detection of breast cancer in dense breasts. To date, the modality has demonstrated greater accuracy than digital mammography in women with scattered or heterogeneous breast density. The first DBT unit was approved by the FDA in February 2011. The FDA approval stipulated DBT as an adjunct to 2-D, or conventional, digital mammography.

Other digital modalities complement mammography and DBT. Breast ultrasonography often is performed along with diagnostic digital mammography. In addition, whole-breast ultrasonography is useful as a screening method for occult cancer in women with dense breasts. Breast MR imaging is low in specificity, but the modality is indicated for monitoring response to chemotherapy and integrity of silicone implants; because of its high sensitivity, it is particularly useful as a screening method for women at high risk for breast cancer. As MR-guided biopsy methods have improved, the modality’s importance has increased in breast cancer detection.

When breast imaging departments and centers began replacing film-screen units with digital mammography equipment and incorporating other digital imaging modalities such as breast MR, the transition required substantial changes to workflow. In particular, technologists, radiologists, and support staff had to adjust to new ways of handling images. Although digital breast imaging continues to provide substantial advantages for patients and professionals, the effects of new digital technologies on image acquisition, storage, patient intake, physician interpretation, prior image comparison, costs, and quality control could be temporarily disruptive and require adaptations in the mammography practice environment. Box 1 lists select terms and definitions typically associated with workflow.

**Imaging Informatics**

Early in the transition to digital mammography, radiology departments were among the most sophisticated electronic departments in most health care settings and among the earliest users of electronic systems to support clinical workflow. Much of the technological development in radiology corresponded with early electronic health record (EHR) advancements. For example, although early EHRs, known as clinical information systems, influenced later technology, widespread use of EHRs began in the 1970s when the Department of Veterans Affairs first implemented a computerized patient record system. Digital subtraction angiography was developed late in the 1970s and computed radiography by 1980. Mammography was one of the final radiology modalities to digitize.

Early radiology systems typically existed as separate, closed systems. Before EHRs, traditional paper-based workflow for radiology was confined to the department; it began with receipt of an order to conduct an examination and ended with sending a report to the referring physician. Although the first RIS was developed in the 1960s, in the mid-1980s formal efforts took place to design features in RIS software that would enhance clinical workflow, along with tracking film. In the late 1990s and early 2000s, PACS technology became more established and widespread. The combination of advancements in clinical digital imaging technology, PACS, and health informatics led to the transition away from paper and toward fully electronic departments.

Mammography lagged behind other modalities in the fully digital conversion for several reasons. Because it is a highly regulated modality, certain restrictions are placed on image compression of mammograms.
Compression of images enables more rapid transmission and reduces image storage requirements. Lossy compression, which affects image quality and can cause a minimal loss of data, is not allowed under the MQSA. As a result, image file sizes for mammograms were larger than for many other types of examinations.

The problem of file size for mammograms was complicated further during breast imaging centers’ transition to digital mammography by the storage and viewing of prior mammograms. A facility’s staff could choose to scan prior analog mammograms and store them digitally so the radiologist could view them along with the new digital images, but the digitized films required even more storage capacity than did the digitally acquired images, which could take up an unreasonable portion of a facility’s PACS capacity. Alternatively, the breast imaging department could purchase a mini-PACS that managed only mammograms, but this further isolated mammography data from the rest of the department.

Throughout the early years of digital mammography adoption, several informatics associations worked closely with professional medical societies and vendors to support improved integration and interoperability of mammography, particularly through development of standards. Eventually, many of the problems associated with transmitting, storing, and displaying digital mammograms were solved, and once digital mammography became ubiquitous, there was less concern regarding scanning of prior mammograms. Further integrating digital breast imaging, particularly DBT, also will depend on past, current, and future efforts at improving imaging informatics and workflow such as:

- Digital Imaging and Communications in Medicine (DICOM).
- Health Level 7 (HL7).
- Integrating the Healthcare Enterprise (IHE).
- Clinical Decision Support.
- Imaging 3.0.
- Meaningful Use.

Digital Imaging and Communications in Medicine

DICOM represents one of the most important steps toward exchanging image information. The international standard, published by the National Electronic

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**Table 1**

**Digital Breast Imaging Workflow Select Terms**

The following terms are associated with workflow issues in breast imaging or with the technology involved in electronic workflow.

**Dashboard.** On computer and digital modality workstations, the dashboard is much like a menu display of important items and indicators. It is similar to an automobile dashboard, enabling users to view at a glance what is happening or available on the unit.

**Digital Imaging in Communications and Medicine (DICOM).** The international standard for defining formats of medical images and the data that enables image exchange.

**Electronic health record (EHR).** Also called an electronic medical record, it is the chronological electronic recording and storage of patient health information generated by encounters in any health care setting.

**False positive.** Any positive finding on a mammogram report paired with a negative breast cancer diagnosis within 12 months of the positive finding.

**Lexicon.** A standardized set of terms.

**Recall rate.** A measure of the percentage of patients receiving screening mammograms who are asked to return for additional imaging assessment.

**Workflow.** The progression of tasks or steps that make up a work process. In the practice environment, people perform tasks and actions such as checking in patients or acquiring images. People also use computers and clinical equipment with software that depends on electronic workflow. In this case, workflow refers to specific steps that occur in a technical framework that enable computerized systems to function, communicate with one another, facilitate data transmission, support the workflow of the people who use them, and ultimately ensure accurate and quality patient care.

**Workflow step.** One of any identified tasks or units of work within a workflow or enterprise that contributes to an overall goal. The step also can be called an activity or business process.

**Worklist.** In electronic workflows, the worklist is a list of items associated with a workflow user. The worklist should contain scheduled steps or work items in a procedure that a person or device performs within the workflow.
Manufacturers Association and the ACR in 1993, defines the formats in which imaging equipment can exchange image data. The standard was refined over years, with involvement from hundreds of people representing the radiology industry, information technology, government organizations, and manufacturers. Working groups represent specific areas within health care including specialties such as radiation therapy and dentistry. The Digital Mammography and CAD working group addresses breast imaging.

Information objects related to imaging workflow are specific to modalities. A 2004 supplement to the DICOM standard provided formatting for radiologist interpretation of breast imaging examinations. Specific encoding supports the physician’s narrative text and Breast Imaging-Reporting and Data System (BI-RADS) categories and assists in storing and transmitting images for sharing with referring physicians or specialists. Information objects also are in place for DBT.

Each digital breast image should have an attached DICOM header with information regarding image display, storage, and retrieval. DICOM conformance is now standard for imaging equipment, and vendors describe technical details of their conformance in a set document format. Vendors should be able to provide a DICOM conformance statement for each piece of imaging equipment that declares the unit’s interoperability and DICOM functionality.

**Health Level 7**

Whereas DICOM is associated with images, another international standard supports electronic health information, specifically EHRs. Developed in 1987, HL7 is an international nonprofit organization that helps develop standardized language or components for EHR systems. The organization collaborates with several other organizations and countries. The HL7 language helps ensure various components of an EHR system can communicate regardless of manufacturer and the interoperability of health data.

Without HL7, health information systems could not integrate to exchange data seamlessly. Mammography professionals might rely on interoperation of EHRs, RISs or mammography information systems, along with others such as physician order entry systems.

Primarily, HL7 enables patient registration, examination ordering, and dissemination of mammogram results. Several versions of HL7 have been released since its introduction. Most informatics systems in place by 2014 were using version 2.0 to integrate with other systems. Version 3.0 was updated to format messages with the use of Extensible Markup Language, or XML, the language most commonly used for data sharing on the World Wide Web. HL7 standards and guides to implementation are available at no cost. The Fast Healthcare Interoperability Resources standard combines features from several versions of HL7, clinical document architecture, and the latest Web standards to improve implementation of HL7. Considered the “next generation” HL7 standard, the newest effort should improve how EHR systems operate.

As of October 2015, 5 major EHR vendors had begun testing a Substitutable Medical Applications and Resuable Technologies, or SMART, application programming interface into their EHR applications based on the new HL7 interoperability standards.

**Integrating the Healthcare Enterprise**

Even with development of standards for language in imaging and health information, early digital imaging equipment and EHR systems were far from interoperable. In fact, as each vendor sought its share of the electronic market, the rush to develop systems caused some industry chaos. Clinical and information systems might have complied with the standards but interpreted them differently enough that problems still occurred. Systems from different vendors could not connect to share information, disrupting electronic workflow and affecting departmental efficiency.

With the parts in place, the industry needed a structure or foundation to bring the parts together. Health care organizations decided to address the problem, and in the late 1990s, the Radiological Society of North America and the Healthcare Information and Management Systems Society met to begin the process. Professionals in health care began IHE to address how computer systems used in medicine could better share information. The initiative started with a radiology working group and expanded to include a number of
domains and technical frameworks. A technical framework is a document organized in detail to guide implementation of integration. Each domain’s framework is specific to the functions and workflow processes of the domain and systems involved. IHE profiles address specific patient care needs by organizing sets of transactions and systems. Vendors prepare integration statements to demonstrate their product’s conformance with the appropriate technical frameworks.43

By addressing informatics workflow at the technical level, IHE has supported transitions to fully digital modalities and departments. The organization added a supplement for mammography workflow in 2007 that addressed issues such as DICOM notations, image transfer, CAD, and workflow steps.44,45 In 2012, a technical framework white paper addressed breast screening process issues. In particular, the working group for IHE provided profiles for managing workflow across the health care enterprise, or before and after examinations were acquired in the breast imaging department.39

New Role of Informatics in Workflow

The capabilities of—and expectations for—electronic systems in health care have evolved beyond tasks such as gathering data, tracking films and reports, or transmitting images. Today’s systems should not only support but also improve a department’s workflow and efficiency and enhance the patient’s experience. These systems must now manage image information that is more complex than ever such as processing 3-D breast images. Regulations, standards, and public policies increasingly require departments to track performance standards and provide both clinical and business metrics.23

Clinical Decision Support

An emerging trend in health informatics is electronic clinical decision support. The process integrates tools, such as ACR appropriateness criteria, into order entry in radiology department processes. This differs from the type of utilization review that insurers and third-party vendors provide, which might not be based completely on clinical evidence. Clinical decision support can provide algorithms through which referring clinicians can view recently performed examinations for possible duplication, note contrast medium allergies, and ensure appropriate examination indications or contraindications.34,35

Most importantly, clinical decision support is specific to each patient and takes advantage of technology to filter available tools and clinical evidence to match the patient at the time of order entry.36 Similar examples in breast screening include entry of clinical data into mammography information systems that helps identify women at higher risk for breast cancer who might need MR examinations according to published screening recommendations, or who might consider genetic testing.46

Use of clinical decision support is slated as a requirement for Medicare under new legislation that takes effect in 2017. The ACR has recognized the requirement as an opportunity for radiologists to highlight the specialty’s role as imaging consultants, to minimize incorrect ordering of examinations by referring clinicians, and to improve examination appropriateness. If an examination is flagged as unnecessary or inappropriate, the radiologist becomes the consultant or collaborator with the physician.37 Clinical decision support must be configured so that it is accurate, rapid, and supports existing processes and workflow.44

Imaging 3.0

Imaging 3.0 is the name given to efforts from the ACR Informatics Committee to represent future informatics and values-based care goals in radiology. The name is modeled after Web 3.0, the endeavor to make the Internet more seamless and interoperable. Imaging 3.0 is designed to address more than the technological aspects of information sharing, however. Because advances have eased information sharing and encouraged enterprise-wide decision-making, the ACR is poised to ensure the role of medical imaging remains efficient in workflow and of high value to referring physicians and patients.37 Many of the principles of Imaging 3.0 already are incorporated into breast imaging practices. For example, BI-RADS is an example of actionable reporting, or a standard lexicon that pinpoints relevant findings referring physicians can act upon.46,47

To address enterprise-wide workflow, Imaging 3.0 includes the workflow steps along the radiology care continuum: before images are acquired, during and after image acquisition, and during and after radiologist
interpretation. Informatics tools might address actions taken when a referring physician considers an imaging examination and concludes with delivery of a report, image, or recommended action to the physician, and sometimes to the patient.

For example, the model likely would consider aspects of managing patient notification for screening mammogram reports. It also could provide greater transparency for patients and empower them with information to allay fears and help them be part of the decision to act on results. A cited case study is the breast density consultation initiative developed by radiologists at Weill Cornell Medical College/New York-Presbyterian Hospital in New York City.20,46

In response to legislation regarding patient breast density notification in New York and the actions of a local patient advocate, radiologists at Weill Cornell Medical College/New York-Presbyterian Hospital implemented a consultation service to help ease the fears and confusion of the nearly 45% of their patients who receive breast density notification letters. The radiologists provide the consultation contact number in the letter and in on-site education materials. A radiologist assistant manages the consultations. He or she answers patients’ questions, in person or via telephone; discusses dense breast screening options with patients; and, if patients request, schedules a meeting for them to speak with the radiologist. In addition to easing patients’ fears, consultations help patients and physicians choose the most appropriate additional screening examination.50

According to McGinty et al, Imaging 3.0 principles can help radiology practices improve workflow by better documenting and improving processes. With a patient-centered approach to informatics and workflow, the model seeks to refine departmental processes to enhance community care. Examples include radiation dose monitoring, identifying opportunities for technologists to reduce dose, and determining ways all staff can decrease patient wait times. Before acquisition, electronic clinical decision support tools could be driven by established practices that have involved radiology and physics professionals in their development such as Image Wisely and Medical Imaging and Technology Alliance Smart Dose standards.37

During acquisition, Imaging 3.0 promotes streamlining of processes, such as comparison with prior examinations, particularly if the comparison delays reporting of results. Radiology departments should work with information technology staff and facility leadership to ensure efficient workflow in image storage, archival, and retrieval. Reporting requires embracing mobile platforms and working with information technology and security experts to ensure privacy of information while delivering results as quickly and accurately as possible.37

**Meaningful Use**

To encourage adoption of certified EHR technology, the federal government initiated a program that rewards use of EHRs for particular purposes. Called *Meaningful Use*, the program provides incentives under Medicare and Medicaid (see Box 2). Participating providers gathered data in 2011 and 2012 as stage 1 of the program and were required to list a number of core objectives, including a minimum number of objectives from a provided list. Stage 2 emphasized clinical processes. Stage 3, which is planned for 2016, requires providers to demonstrate use of EHR technology to promote exchange of health information and improve health outcomes for patients.48,50

Screening mammography is a clinical quality measure under stage 1 of Meaningful Use. Providers are measured per the National Committee on Quality Assurance (NCQA) standards on the percentage of women aged 40 through 69 years who have had a screening mammogram in the past 24 months.51 According to the Agency for Healthcare Research and Quality, screening for breast cancer is a way in which providers can assist with disease surveillance and quality improvement in their populations.52 RIS and mammography information system vendors have been working to ensure their systems qualify as certified EHR technology.34,46

Radiology departments also can adopt principles of Imaging 3.0 to work toward meeting Meaningful Use criteria. For example, the work in the case study at Weill Cornell Medical College/New York-Presbyterian Hospital involving breast density education engages patients and can lead to improved quality of care and
Traditionally, when findings suggestive of malignancy are reported on screening mammograms or clinical breast examinations, a patient might have diagnostic mammography followed by ultrasonography, breast MR, or DBT. Recently, DBT has become increasingly important as a follow-up tool, particularly in women who have dense breasts. The decision on imaging beyond mammography is based largely on BI-RADS category and can be aided by decision support tools.

**Ultrasonography**

Ultrasonography is used to evaluate and characterize certain round or oval masses, especially to distinguish cystic masses from solid ones; subcategorize solid masses as probably benign to facilitate short-term surveillance and minimize unnecessary biopsies; evaluate architectural distortion and asymmetry; and guide biopsy procedures. Ultrasonography is indicated in high-risk women, such as those with first-degree relatives with breast cancer, if they cannot have MR imaging. Ultrasonography is second in preference to MR for many women with intermediate risk such as those who have lobular neoplasia.

Ultrasonography typically is the initial examination performed in men younger than age 25 with a palpable but indeterminate breast mass and complements mammography when there is high suspicion for breast cancer in men of any age upon physical examination by a physician. Adding ultrasonography to mammography has improved specificity of breast lesion diagnosis and led to fewer biopsies with negative findings.

Whole-breast ultrasonography has proved helpful in locating small, occult malignancies in dense breasts. Reimbursement for ultrasonography has been mandated in some states for women who receive dense breast notification. Recent revisions to the BI-RADS lexicon included breast density descriptions of tissue composition for sonogram reporting to better correlate with those descriptions used for mammogram interpretation, which could improve reporting time and workflow.

Automated whole-breast ultrasonography could provide a screening examination, performed by technologists, for women who have dense breasts. The digital images can be saved for later review by a radiologist.
This solution could require additional costs for technologists, physical space, and equipment.57

**Magnetic Resonance Imaging**  
Breast MR imaging has several uses, most notably as an additional screening modality for women at high risk of breast cancer. The American Cancer Society added breast MR screening examinations to their screening recommendations for women with a minimum of 20% lifetime risk of breast cancer because the combination has the highest sensitivity for detecting breast cancer. This includes women who have the *BRCA* mutation and those with strong family history of breast or ovarian cancer.5 These women should have both mammography and breast MR. Women at intermediate risk of breast cancer might have breast MR, but screening mammography is the preferred imaging method.65

MR examinations also are used to monitor response to breast cancer treatment and to evaluate integrity of silicone breast implants. This imaging examination uses a separate protocol from a breast cancer screening examination.1 In the past, there was no BI-RADS lexicon terminology for implant evaluation, but a revision includes a new section for implants. The revised BI-RADS lexicon for MR also altered terminology for background parenchymal enhancement and for describing the amount of fibroglandular tissue present to improve descriptions of dense breast tissue and to better correlate the descriptions to mammography findings, also improving reporting workflow.64

In some radiology departments or breast imaging centers, patients having breast MR imaging have their examinations on dedicated breast MR equipment. In other departments, breast MR examinations occur on whole-body MR equipment with the assistance of dedicated tables with breast coils or detachable coils that can be used on standard tables.50 When breast imaging is completed on standard equipment, breast imaging workflow must be integrated with other MR examinations.50

**Digital Breast Tomosynthesis**  
A discussion of digital mammography workflow is incomplete without addressing the effects of the increasing use of DBT in breast imaging, which was approved by the FDA as an adjunct to digital mammography.7–22 In other words, every DBT screening study must be accompanied by a full 2-D mammogram. The rationale for the FDA requirement is to ensure interpreting physicians can detect clustered microcalcifications at the same level as possible with standard mammograms. Although physicians can easily evaluate calcifications on DBT images, it can be difficult to detect unknown clusters of calcifications because each single calcification can appear in a different plane on DBT.7

Much of the increase in use of DBT is because of the emphasis on breast density and legislation regarding notification of women with dense breast tissue on screening mammograms.17,57

**Technique and Acceptance**  
DBT is a 3-D reconstruction tomosynthesis technique, with each thin slice in sharp focus minimizing the inherent problem of mammography caused by overlapping tissue.6,61 In effect, DBT can be considered an extension of digital mammography.62 In a DBT acquisition, the patient’s breast is compressed, and the x-ray tube source moves at a low angle of arc around the breast to acquire images from various directions. An examination involves a preset series of low-dose images at pulsed intervals. Because all of the images are synthesized together, each requires less radiation dose, so the total dose delivered during the examination is roughly equal to that of a 2-D mammogram.7,14,21

Because the FDA requires the accompanying 2-D mammogram, total radiation dose actually is greater than with DBT alone. However, DBT is indicated mostly for women with dense breasts for screening mammogram. By the time a woman is in her 40s, her breasts are likely resistant to the level of medical radiation delivered by the synthesized examination.7

Sensitivity of mammograms in dense breast tissue drops substantially.63 The modality has proved to be particularly effective in detecting invasive cancers.64 Several studies have shown the positive effects of DBT on reducing recall rates.24 The rates are particularly notable when studies also demonstrate an increase in cancer detection through use of DBT.64 Recall rates have been cited by various opponents of screening...
mammography as a reason women in their 40s who are not at risk for breast cancer should not undergo regular screening.7

DBT also is better than conventional mammograms for diagnostic evaluation of lesions identified at screening, but the cost of the technology is too high to justify its use for a diagnostic modality alone, and it has proved valuable as a screening add-on.7 Although adding DBT increases costs, the average cost of acquiring a DBT examination was less in 2014 than for a 30-minute MR examination.57 Reimbursement for DBT was uncertain when the modality first entered the breast imaging market. In many instances, patients have had to opt for the technology with the understanding that they also would have to pay for DBT.14,65

When the FDA began requiring the combination of DBT and 2-D digital mammography, the Centers for Medicare & Medicaid Services (CMS) announced a payment rate and Current Procedural Terminology (CPT) code to use for reimbursement of the examinations under the Medicare Physician Fee Schedule. Although having a reimbursement method facilitates payment, valuing the combination examination before gathering data to assess DBT as a stand-alone examination could make it difficult to accurately determine reimbursement for the new technology, according to the ACR.66

Workflow

When a breast imaging center adds DBT, the new imaging method can affect workflow temporarily and cause permanent adjustments. The lengthier interpretation time is an example of potential long-term changes to workflow. In the short term, radiologic technologists might not work as efficiently in acquiring images, and radiologists might need additional time interpreting them until they become more experienced. Practice leaders must consider time and money spent on training clinical and administrative staff.14

Interpretation time is lengthier even for radiologists with experience evaluating DBT images. One study found physicians who had 17 months or more of experience interpreting DBT examinations needed nearly 47% more time to interpret the combination of DBT and digital mammograms than they needed to interpret the mammograms only.14 Even so, because DBT images are acquired in the same projections as the mammograms, radiologists learning to interpret DBT images already are familiar with DBT patterns and structures. The difference with DBT is that anatomy and pathology are clearer because of the lack of superimposition of tissue layers possibly obscuring lesions.7

A primary workflow advantage of DBT is the technique’s incorporation into mammography equipment. DBT can be built into newer units.57 When acquiring a companion digital mammography examination, the patient’s breast remains in compression while the mammographer acquires the conventional digital mammogram in the same projection as the sequential DBT data sets.14,21,57 This saves patients and radiologic technologists time vs transfer to another suite for ultrasonography or breast MR examinations. The combined techniques of mammography and DBT can reduce training needs and save physical space. Streamlined equipment with DBT also can reduce the time and costs associated with ongoing maintenance and quality assurance.57

The reduced false-positive rates and resulting reduction in recall examinations from adding DBT can positively affect workflow. Radiologists spend less time interpreting negative recall examinations.14 In addition to reducing the number of recalls, DBT images do not need placement of radiopaque markers for skin lesions or nipples.14 Diagnostic breast examinations typically take more time than screening examinations and are less cost-effective. It is possible that DBT can eliminate the need for some diagnostic mammography studies, such as spot compression projections, in addition to the technique’s positive effect on recalls.57 In fact, Peppard et al reported spot compression images seldom yield additional information after DBT images with the exception of calcifications.14 In short, the authors suggested that use of DBT can improve use of resources and lead to faster diagnostic workups.11

Schrading et al studied the performance of DBT for image guidance in vacuum-assisted breast biopsies.67 The authors concluded biopsies performed with DBT guidance took less time (an average of 13 minutes) than those performed with prone stereotactic guidance (average of 29 minutes) in a study involving 216 suspicious mammographic findings, split nearly evenly
Informatics in Medicine (SIIM) joined representatives of the ACR and the American Association of Physicists in Medicine to develop the parameters for determinants of image quality in digital mammography. As of the 2014 revision, 3-D reconstruction techniques, such as DBT, were not addressed in the parameters.\textsuperscript{69}

**Image Retrieval and Comparison**

Rapid image retrieval is critical to interpreting physicians but also to referring physicians who need timely reports and images to take the next critical step in patient care.\textsuperscript{67} Workflow involves both storage and extraction of data including reports and images. Radiologists, mammographers, referring clinicians, and breast imaging staff might need to retrieve images. Informatics advancements have led to improved speed and accuracy of storage and retrieval, but mammography workflow must have a process for consistent procedures for image transmission and retrieval.\textsuperscript{28,37,69} Digital mammography parameters, which include Integrating the Healthcare Enterprise image integration profiles, recommend that mammograms stored locally should display on a workstation within 3 seconds.\textsuperscript{69}

Control of retrieval time for archived images, such as comparison mammograms or for image transmission to a referring physician, is more difficult. For example, a mammography provider cannot control the network speed of a physician office that is not within the same health care organization.\textsuperscript{69} Automated image retrieval is a burgeoning field of informatics, not only in health care but in other industries as well. Content-based image retrieval queries that could support CAD by calling up images with similar pathology for the radiologist to compare. For example, lesion size, shape, and other features used in the BI-RADS lexicon could help physicians compare similar images.\textsuperscript{70} Ability to retrieve a specific patient’s prior images for comparison when interpreting current mammograms is essential in interpreting new studies\textsuperscript{69} and an important contributor to reduction in recall rates, regardless of whether the interpreter has available only 2-D digital mammograms or both DBT and mammograms for the current study. When simultaneously reviewing previous studies, the interpreter can note any changes over time.
and assess whether a potential abnormality might have been present on previous images but represents a steady, benign finding. Quality parameters for digital mammography require that image displays for interpreting physicians simultaneously display sets of current and previous conventional 4-projection screening mammograms.

If a practice maintains film-screen mammograms for previous comparison, the films still can be digitized, stored, and imported from portable media, but the digitized mammograms will require large amounts of data storage. Even though analog studies are digitized for comparison on soft-copy display, the FDA requires that practices also keep original films in storage for archival purposes.

**Interpretation and Reporting Time**

Past issues with radiologists having to compare soft-copy digital images to prior hard-copy or digitized film-screen mammograms largely have been resolved now that digital mammography is virtually standard. Other interpretation workflow problems have been solved with the ubiquity of digital mammography. For example, mammographers often used to hang film-screen mammograms on viewboxes with the emulsion side facing outward to reduce glare for the interpreting radiologist. This reversed the order of images, placing the right craniocaudal image to the right of the left craniocaudal image, and the right mediolateral oblique to the right of the left mediolateral oblique image. Once practices became fully digital, radiologists could switch to viewing mammograms with the radiologic right on the left, which conforms to other medical imaging interpretation workflow. In general, soft-display hanging protocols should be flexible enough to meet the needs of individual users as long as mammograms are labeled and oriented properly.

The transition to increased use of DBT is affecting interpretation time. Studies to date estimate a radiologist review of DBT image sets requires nearly twice as much time as a review of typical digital mammograms. Digital breast imaging practices considering combined DBT and digital mammography must consider this information when determining resources, staffing, and potential reimbursement from examinations.

Studies have shown that radiologists who specialize in breast imaging perform better on interpreting diagnostic mammograms. As radiologists became used to the display tools available, it became apparent that use of tools increases interpretation time and delays reporting; therefore, quality parameters suggest keeping digital mammography display tools to the minimum of window/level and zoom/pan to optimize performance and workflow. Although DBT requires nearly double the interpretation time per examination, some of the workflow reduction is offset by lower recall rates.

Mammography CAD prompts can affect a radiologist’s visual search behaviors, which also can affect workflow. As of this writing, CAD was still investigational for use with DBT, so the algorithms run only on the conventional mammograms. Addition of CAD to DBT images could significantly improve radiologist workflow.

Improvements in technology likely will continue to enhance breast imaging effectiveness and workflow. For example, authors Jinnouchi et al say software developments, such as adaptive control processing, could improve image contrast for individual mammograms and decrease interpretation time. Automated or structured reporting of critical findings is another workflow step that likely can be improved with informatics, although the concept is somewhat controversial. For example, by matching BI-RADS category with automatic reporting of critical findings to the referring physician, digital mammography and supporting systems can improve workflow and lead to a more rapid follow-up for patients who have breast cancer. The Radiological Society of North America’s Reporting Committee has published at least 100 templates for radiology reporting to help standardize reporting language for modalities and various parts of patient anatomy.

**Practice Considerations**

Workflow considerations were critical to the transition from film-screen to digital mammography, and workflow remains important for improvement and new performance measures. For example, patient-centered care principles and Meaningful Use emphasize efficiency and coordination of care, which can be achieved only if processes flow smoothly. This is true of electronic
workflow of information and clinical systems and of staff time.97

To remain successful and to continue to provide excellent care as digital breast imaging technology advances, practices must consider important issues such as attention to standards and regulations, quality measures and improvement, and maintained viability in the form of costs and reimbursement.

Quality Improvement

Digital breast imaging offers clinical and practice advantages such as elimination of lost examinations and improved workflow through integration with information systems.9 New models of quality improvement can help breast imaging providers meet the goals of standard-setting bodies and reward systems and enhance overall patient care. Among these are use of business intelligence analytics and lean principles in health care.

Metrics and Analytics

An example of a workflow step that often needs improvement is patient scheduling. Patient satisfaction, improved clinical outcomes for populations served, efficiency, and care coordination all depend to some extent on a breast imaging center’s ability to have available, convenient appointments and to schedule accurately. However, scheduling involves many procedures that require attention to both electronic and staff workflow. A scheduling system must take into account available physical space, clinical units, and appropriate staff, and must properly sequence the examinations.98

RISs and mammography information systems can track data to help improve digital breast image quality and workflow processes such as patient scheduling. Examples of typical performance metrics for mammography practices include:

- Department operations such as number of patients per day, patients per unit, report turnaround time, and examination repeats.
- Examination measures such as scheduling, patient arrival, availability of previous images, and time from schedule or patient arrival to examination start or completion.
- Image handling such as images available for interpretation, transfer of images to PACS, matching of current and previous images, transfer of images to referrers or archives, and purging of archives.

Business analytics help practices achieve better efficiency by breaking down the steps in processes and workflow to determine where problems occur or improvement can be made. When radiology departments and breast imaging centers use different measurements and terms to track these steps, it is difficult to analyze, compare, or benchmark efforts. Efforts by SIIM to standardize the business analytics lexicon could help create workflow improvement tools. The working group that developed the current lexicon attempted to identify the appropriate level of steps, naming enough to help radiology departments manage and improve steps, but not so many that the task of doing so was burdensome.99 The most recent draft lexicon from 2014 was not specific to mammography but included steps particular to mammography such as time required for clinical follow-up letters.75

Lean Principles

Along with technological advancements have come efforts from organizations to shape and raise new standards for health care delivery. Some health care institutions achieve quality improvement through lean principles. The lean concept first was introduced in the 1950s at Toyota in Japan. This quality system emphasizes workflow and recognizes that all workflows have processes that add value and others that add no value. When health care entities implement lean principles, their leaders judge value based on the patient’s perspective.76

The lean concept aims to eliminate waste and correct mistakes in workflow. Initiatives begin with an organization’s leadership, which should emphasize commitment to the initiative but involve workers at all levels.76 Shah et al reported on an initiative to improve screening mammography workflow using lean principles.77 According to the authors, the team approached the initiative after several failed attempts to improve efficiency in the mammography section.

The team required comprehensive quality improvement after joining a multispecialty breast care center...
and facing increased demands on their time and more complex cases. For 11 months, an interdisciplinary team met regularly to become familiar with lean principles and to implement its evaluation and workflow improvement. Using a patient-centered approach, the team identified areas of value and waste in the screening mammography workflow. They took steps such as silently observing patients, technologists, and radiologists. They implemented trials focused on several key areas to address possible solutions. These included patient wait time, electronic work list, and portable electronic device trials, along with one focused on redefining roles.

As a result of the lean initiative, the authors reported that patient wait times decreased by 70%, from 11.1 minutes to 3.3 minutes. Other trials improved radiologist efficiency, which in turn provided screening results to patients sooner. A trial appointing a lead technologist for the day, along with a visual communication trial, improved flow of the physical space and technologist time by eliminating the need to search for an open examination room. Overall, the authors reported that the team improved efficiency and decreased patient wait times using lean principles.77

**Costs and Reimbursement**

Early in its adoption, digital mammography was associated with substantial start-up costs, particularly for equipment and workstations. According to Lee and Lehman, the transition to digital mammography had already begun by the time a 2008 analysis comparing its cost-effectiveness to film-screen mammography was published. The study showed digital mammography was no more cost-effective than its predecessor. In fact, it could be more costly overall because of high false-positive rates associated with the screening examinations.15

DBT also is associated with high upfront costs, although the examination cost is relatively affordable, particularly when compared with breast MR.12,97 Practices also must consider training associated with DBT. The MQSA requires radiologists to have 8 hours of dedicated DBT training before interpreting images on their own, and radiologic technologists acquiring DBT images also must have 8 hours of training in DBT technology before acquiring the images independently.44

As radiology departments continue to upgrade digital mammography units, store prior images, and add DBT, they must consider PACS storage requirements. Combined digital mammography and DBT examinations are substantial, from 100 to 200 times the size of the digital mammography examination alone, depending on whether all raw slices are archived.44

Rapid adoption of digital mammography coincided more with the announcement of reimbursement for the examination for Medicare patients than with FDA approval, although the reimbursement announcement followed closely behind the clinical approval.57 Before the CMS added CPT codes for DBT, patients whose insurance did not pay for the additional imaging had to pay for the examination themselves. Practices can bill patients who are not covered under the Medicare Physician Fee Schedule or whose insurance has chosen not to pay for DBT. It typically is standard to ask patients to opt for DBT and to sign a waiver saying that they will pay for the examination, which averaged $69 as of early 2015.44 Manufacturers of DBT units have been marketing directly to consumers who might be willing to pay for the DBT portion of their mammograms.57 As of May 2015, most private insurers did not cover DBT, forcing practices to ask the patient to pay for the examination, or to write off the cost.78

Much like digital mammography, the high cost of early adoption of DBT technology can be partially offset by higher Medicare reimbursement early in the technology’s introduction.78 As of February 2015, the ACR reported that a screening digital mammogram was reimbursed by Medicare at $134.80, and billed with a G code. The combined digital mammography and DBT examination, billed with a G code and add-on code, paid $134.80 plus an additional $56.13. CMS also allowed billing of combined digital and DBT examinations for unilateral and bilateral diagnostic mammograms but created no avenue for billing diagnostic DBT as a stand-alone examination.56,79

**Role of the Technologist**

Technologists must ensure they can acquire images at optimal quality and patient dose when learning new technology, regardless of time involved in workflow.44,49 This includes the use of high-resolution DICOM-compatible workstations when acquiring
discovering ways to reduce patient dose, decrease wait times, assist in communication of findings, or improve clinical processes, radiologic technologists support the meaningful use of technology and their organization’s goals to care for the patients they serve.\(^7\)

**Conclusion**

The quest to improve efficiency in radiology, including breast imaging, through the use of advanced clinical technology and improved information technology is a continual effort that will continue far into the future.\(^6\) Although advances can seem disruptive while in transition from one new method or modality to another, or when implementing new informatics and software upgrades, informatics ultimately contribute to greater efficiency and have the potential to improve breast imaging workflow.\(^5,30,37\)

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**References**


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Digital Breast Imaging Workflow

Read the preceding Directed Reading and choose the answer that is most correct based on the article.

1. Which of the following statements is false regarding 1970s xeromammography?
   a. The technique resembled photocopying.
   b. Images were printed on paper with blue powder.
   c. The technique was one of the most efficient breast imaging techniques in terms of workflow.
   d. Concerns about radiation dose were among those that led physicians back to film-screen methods.

2. The Digital Mammographic Imaging Screening Trial demonstrated that digital mammograms were clinically:
   a. superior to film-screen mammograms.
   b. inferior to film-screen mammograms.
   c. superior for all women except those older than 50 years or with dense breasts.
   d. comparable to film-screen mammograms and superior in sensitivity for women younger than 50 or with dense breasts.

3. Which of the following is not an advantage of digital mammography over film-screen examinations?
   a. improved workflow
   b. reduced costs
   c. reduced radiation dose to the patient
   d. lower likelihood of lost examinations

4. By 2014, digital mammography constituted more than ______ % of the U.S. market.
   a. 50
   b. 60
   c. 80
   d. 90

5. As of fall 2015, at least 24 states had passed a law requiring patient letters sent after mammograms to include:
   a. notification of high fibroglandular tissue.
   b. availability of digital breast tomosynthesis.
   c. new breast cancer screening recommendations.
   d. Breast Imaging-Reporting and Data System (BI-RADS) lexicon instead of lay language.
6. Advancements in which technologies led to the transition from paper to electronic radiology departments?
   a. digital imaging technology
   b. health informatics
   c. picture archiving and communication systems

   a. 1 and 2
   b. 1 and 3
   c. 2 and 3
   d. 1, 2, and 3

7. Image file sizes for mammograms are larger than for many other types of examinations largely because of:
   a. the number of projections.
   b. image resolution.
   c. Mammography Quality Standards Act requirements that prohibit lossy compression.
   d. wider dynamic range.

8. Efforts at improving imaging informatics and workflow include all of the following **except**:
   a. Health Level 7 (HL7).
   b. Integrating the Healthcare Enterprise (IHE).
   d. computer-aided detection (CAD).

9. _______ is the international standard that defines formats in which imaging equipment can exchange image data.
   a. IHE
   b. Digital Imaging and Communications in Medicine (DICOM)
   c. HL7
   d. Imaging 3.0

10. _______ language helps ensure various health information components can communicate, regardless of manufacturer.
    a. IHE
    b. DICOM
    c. HL7
    d. Imaging 3.0

11. A document organized in detail to guide implementation of integration of clinical and information systems in health care is known as a(n):
    a. conformance statement.
    b. integration statement.
    c. technical supplement.
    d. technical framework.

12. Which of the following statements is **false** about clinical decision support?
    a. The process is the same as utilization review.
    b. It integrates tools such as American College of Radiology (ACR) appropriateness criteria.
    c. Medicare likely will require use of clinical decision support beginning in 2017.
    d. It is specific to individual patients.

13. Use of clinical decision support is slated as a requirement for Medicare under new legislation that will take effect in:
    a. 2016.
    c. 2018.
    d. 2019.

14. BI-RADS is an example of actionable reporting.
    a. true
    b. false
15. A breast density education initiative in New York City provides patients who have dense breasts a contact number for consultations. The consultations are managed by a:
   a. radiologist.
   b. nurse.
   c. radiologist assistant.
   d. scheduler.

16. Meaningful Use is a federal program initiated to reward use of which of the following?
   a. certified mammography facilities
   b. certified electronic health record (EHR) technology
   c. breast density notification
   d. combined digital mammography and digital breast tomosynthesis (DBT)

17. The initial breast imaging examination for men younger than age 25 who have a palpable but indeterminate mass is:
   a. screening mammography.
   b. magnetic resonance (MR) imaging.
   c. DBT.
   d. ultrasonography.

18. BI-RADS revisions added lexicon terminology to the MR section for:
   1. implant evaluation.
   2. background parenchymal enhancement.
   3. amount of fibroglandular tissue.
   a. 1 and 2
   b. 1 and 3
   c. 2 and 3
   d. 1, 2, and 3

19. The U.S. Food and Drug Administration approved use of DBT as a(n):
   a. stand-alone screening examination only.
   b. stand-alone diagnostic examination only.
   c. adjunct to 2-D digital mammography.
   d. option only in women with microcalcifications.

20. By the time a woman is in her 40s, her breasts are likely resistant to the level of medical radiation delivered by a digital breast tomosynthesis examination.
   a. true
   b. false

21. Which of the following statements is false regarding physician interpretation of DBT images?
   a. Since projections are the same as mammography, physicians are familiar with DBT patterns and structures.
   b. Interpretation time is longer only for radiologists with no experience evaluating DBT images.
   c. Anatomy and pathology are clearer because there is no superimposition of tissues on DBT.
   d. Interpretation from DBT results in lower false-positive rates.

22. Use of DBT could increase the need for spot compression studies.
   a. true
   b. false

23. An analysis of retakes in digital mammography by Prieto et al revealed 40% of the retakes contributed to positioning errors were caused by:
   a. small detector panels.
   b. patient movement after technologist positioning.
   c. inexperience with digital mammography.
   d. overcompression.

24. Digital mammography parameters recommend locally stored mammograms display on a workstation within ________ seconds.
   a. 3
   b. 5
   c. 15
   d. 30

continued on next page
25. Soft-display hanging protocols for digital mammograms should:
   a. match those of other digital radiology modalities.
   b. follow the same method as previous film-screen, or hard-copy, protocols.
   c. be flexible enough for individual users, but labeled and oriented properly.
   d. not vary according to manufacturer.

26. CAD can:
   1. affect a radiologist's visual search behaviors.
   2. improve radiologist workflow when added to DBT.
   3. improve results with DBT algorithms.
   a. 1 and 2
   b. 1 and 3
   c. 2 and 3
   d. 1, 2, and 3

27. The Society for Imaging Informatics in Medicine is attempting to standardize the ______ to help create workflow improvement tools.
   a. mammography admission steps
   b. BI-RADS lexicon
   c. business analytics lexicon
   d. EHR networking framework

28. Lean principles judge ______ in workflow based on the ______ perspective.
   a. performance; leader’s
   b. performance; patient’s
   c. value; leader’s
   d. value; patient’s

29. The MQSA requires that radiologic technologists have ______ hours of training in DBT technology before acquiring images independently.
   a. 0
   b. 8
   c. 12
   d. 24

30. Which of the following is true of DBT documentation for reimbursement purposes?
   a. Technologists and radiologists need to document only the DBT projections.
   b. Now that DBT has been approved for its own stand-alone reimbursement, it is important to document the conventional digital mammogram as a separate examination.
   c. The Centers for Medicare & Medicaid Services has not created an avenue for billing diagnostic DBT as a stand-alone examination.
   d. No documentation is needed for DBT until the technique has its own code.